IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Sgouros, G. et al.	§	**ART UNIT:**
	§	**1618**
FILED: November 24, 2003	§	
	§	**EXAMINER:**
SERIAL NO. 10/720,904	§	**Perreira**
M.J.		
	§	
FOR: Liposomal Encapsulation of Alpha Particle Emitters and Uses Thereof	§	**DOCKET:**
	§	**D6348CIP**

MS NON-FEE AMENDMENT
The Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

In response to the Restriction Requirement in the Examiner's communication mailed April 2nd, 2007, Applicants hereby provisionally elect, with traverse, Group II, claims 20-33, drawn to a method of targeting cells in an individual for liposomal delivery of an alpha particle-emitting radionuclide. Further, in response to species election, Applicants elect without traverse antibodies, peptides, engineered molecules or fragments thereof as targeting molecules (claims 20-33), wherein at least some of the antibodies are Herceptin (Claim 25), cancer cells, virally infected cells, autoimmune cells or inflammatory cells are the targeted cells (Claim 26), phosphate buffer, insoluble metal binding polymers, resin beads, metal-binding molecules or halogen binding molecules as stabilizing agents (claims 27-28), ^{225}Ac, ^{223}Ra, ^{213}Bi, or ^{211}At are the alpha-particle emitting radionuclides (claim 31) or the

alpha-emitting radionuclide is a daughter of a beta-particle emitting radionuclide, wherein the beta-particle emitting radionuclide is ^{212}Pb (claims 32-33).

Applicants further request that Group III, claims 34-42 be rejoined with Group II, claims 20-33 for examination. Group III is drawn to a method of targeting cells expressing HER-2/neu protein in an individual for liposomal delivery of ^{225}Ac. The Examiner contends that these methods are unrelated as they may be performed with different liposomal compositions and may include different method steps. Further, the Examiner states that the method of Group II involves targeting cells with a liposomal composition while the method of Group III is a method of targeting cells expressing HER-2/neu which don't necessarily require the same liposomal composition and would be capable of being performed in a distinct manner. Applicants respectfully disagree.

Applicants submit that in general both the methods involve encapsulation of a radionuclide within an immunoliposome coated with molecules that enable targeting of the liposome to specific cells to reduce the loss of radioactive decay intermediates from the targeting vehicle and at the same time reduce non-tumor specific uptake of the radionuclide containing liposomes. Both, Group II and Group III liposomal compositions involve entrapping radionuclide in a small liposomal vesicles; incorporating the thus entrapped radionuclide into the aqueous phase of a larger liposomes, which are large enough in diameter to retain the radioactive decay intermediates of the incorporated radionuclide, polyethylene glycol-linked lipids on the outer

membrane of the large liposome and a targeting agent. The radionuclides used by both compositions decay by the emission of alpha-particles that are high linear energy transfer(LET) radiation and are short-range, thereby reducing the so called "by-stander killing effect". The energy range for these particles is between 4.0 and 8.8 MeV.

Hence, the liposomal composition of Group III is also encompassed by Group II as ^{225}Ac, the radionuclide used specifically in the liposomal composition of Group III, is one of the radionuclides recited amongst other alpha-particle emitting radionuclides that can be incorporated in the liposome of Group II. In addition, Her-2/neu, the targeting molecule used in the liposomal composition of Group III, is listed as one of the tumor specific antigen used for targeting amongst other targeting molecules that can be utilized in the liposome of Group II. Thus, both the methods have similar modes of operation, similar function and effects and can be used together. As a result prior art search for inventions of Group II will also encompass invention of Group III and therefore will not pose a serious burden on the Examiner. Hence, an examination of these groups together should not pose undue burden on the Examiner. Accordingly, the Applicant respectfully requests that Group III, claims 34-42 be rejoined with Group II, claims 20-33 for examination.

Applicants enclose a Power of Attorney and Correspondence Address Indication Form with a Statement under 37 CFR §3.73(b) signed by Mr. Gustave J. Bernhardt as representative of the Assignee, Sloan-Kettering Institute for Cancer Research. In addition Applicants enclose a Petition for a

Two Month Extension of Time. Please charge the $225 extension fee under 35 CFR §1.17(a) to the credit card identified on Form PTO-2038. Only in the absence of Form PTO-2038, please debit any applicable fees from Deposit Account No. 07-1185 upon which the undersigned is allowed to draw.

Respectfully submitted,

Date: Jun 13, 2007

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